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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/853,409	05/11/2001	Kevin P. Anderson	ISPH-0569	7066

26259 7590 01/14/2003

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EXAMINER

GUZO, DAVID

ART UNIT	PAPER NUMBER
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1636

DATE MAILED: 01/14/2003

[Signature] 12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

Applicant(s)

09/853,409

ANDERSON ET AL.

Examiner

Art Unit

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Pri rity under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>Z</u> . | 6) <input type="checkbox"/> Other: _____. |

Detailed Action

Applicant's election with traverse of Group IV, claims 23-24 in Paper No. 11 is acknowledged. The traversal is on the ground(s) that all of the claims relate to the single concept of treatment of HCV associated disease and that the different Groups are not novel and unobvious over each other. Applicants also assert that a search relating to treatment of HCV associated disease would identify art related to all the claims in the application. This is not found persuasive because clearly the claims in Group IV do not read on methods of treatment of HCV associated disease. Indeed, claim 23 recites a composition comprising any oligonucleotide (which reads on oligonucleotide decoys, antisense molecules, sense molecules, etc.) independent of target. Claim 24 recites a method for inhibiting expression of a gene in an animal, wherein said method does not involve HCV associated disease. A search of Groups I-III would not identify art on inhibiting non-HCV or HCV associated genes in animals, would not identify art dealing with oligonucleotide decoys, sense strands, etc., would not be co-extensive with a search of the subject matter of Group IV and hence would be burdensome.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Cho-Chung.

Applicants claim a composition comprising an oligonucleotide in a form suitable for subcutaneous administration and a method for inhibiting expression of a gene in an animal comprising administering an antisense oligonucleotide capable of hybridizing to said gene.

Cho-Chung (U.S. Patent 5,627,158, issued 5/6/97, see whole document, particularly column 6, lines 44-64 and Claim 1) recites a composition comprising an antisense oligonucleotide for subcutaneous administration and a method of inhibiting the expression of the $R1\alpha$ encoding gene in animals, said method comprising administering the antisense oligonucleotide to said animal wherein the antisense oligonucleotide binds to and inhibits expression of the target gene. Cho-Chung therefore teaches the claimed invention.

Claims 23-24 are rejected under 35 U.S.C. 102(e) as being anticipated by Feinberg et al.

Applicants' invention is as described above.

Feinberg et al. (U.S. Patent 5,276,017, issued 1/4/94, see whole document, particularly Column 13, lines 52-68 and column 14, lines 1-11) teaches an antisense composition for subcutaneous administration wherein the antisense oligonucleotide is administered to animals and binds to and inhibits the expression of the gene encoding tropho-uteronection (TUN).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 23-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant specification and claims, as originally filed, does not provide support for the broad scope of the claimed subject. The instant application does not provide support for claims broadly reading on **any** oligonucleotide composition (which can be decoy oligonucleotides, sense strand sequences, antisense, etc. directed against **any** target). The application also does not provide support for **inhibiting any gene** in an animal comprising the subcutaneous administration of **any** antisense oligonucleotide. The instant specification provides support for oligonucleotide compositions (which can be formulated for subcutaneous administration) directed against HCV as well as

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methods of inhibiting HCV replication and HCV associated diseases in animals comprising administering an antisense oligonucleotide targeted against an HCV sequence. This is a NEW MATTER rejection.

It is noted that the Declaration improperly claims benefit for the PCT/JP93/01293 application under 35 USC 119. However, the Continuing Data on the first page of the specification properly claims benefit under 35 USC 120 for this PCT application.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Faxes may be submitted directly to the examiner at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo
January 3, 2002

DAVID GUZO
PRIMARY EXAMINER
David Guzo